

REMARKS/ARGUMENTS

The above-identified application has been reviewed in light of the Office Action mailed on December 11, 2008. Claims 1-40 are currently pending. By the present Amendment, Applicants have amended independent Claims 1, 15, 20, 26, 27 and 40. Applicants respectfully submit that the present Amendment does not incorporate any new subject matter and is fully supported by the specification. In addition, Applicants respectfully submit that Claims 1-40 are allowable over the references of record. In view of the amendments to independent Claims 1, 15, 20, 26, 27 and 40 effected herein and the following remarks and arguments, Applicants respectfully request favorable reconsideration and allowance of the above-identified application.

Double Patenting

Claims 1-22, and 25 stand rejected on the ground of nonstatutory obviousness-type patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,226,434. In response thereto, Applicants will file a suitable terminal disclaimer upon indication that the claims are otherwise allowable.

Claim Rejections under 35 U.S.C. § 102

In the Office Action, Claims 1-10, 12-22, 25-29, 31 and 33 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,287,278 to Woehr et al. ("Woehr"). Applicants respectfully submit, however, that Woehr fails to disclose each and every element recited in Claims 1-10, 12-22, 25-29, 31 and 33 as presented herein.

Under 35 U.S.C. § 102(b), to anticipate a claim, a reference must disclose each and every element set forth in the claim. (*See* MPEP 2131).

Independent Claim 1 has been amended to recite, *inter-alia*, a safety shield comprising: a piercing member...a clip defining a first cavity... the clip being movable from a first orientation to a second orientation to reposition the first cavity from a movable orientation to a binding orientation... the clip including a first leg ...the clip further including a second leg having a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation...

Independent Claim 15 has been amended to recite, *inter-alia*, a safety shield comprising: a piercing member...a clip including a plate...the clip being rotatable from a first orientation to a second orientation to reposition the cavity relative to the longitudinal axis of the piercing member from a sliding orientation to a binding orientation... the clip including a first leg ...the clip including a second leg that extends from the plate and has a proximal part and a distal part, the distal part of the second leg including a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation...

Independent Claim 20 has been amended to recite, *inter-alia*, a safety needle shield apparatus comprising: a needle...a clip including a plate oriented in an axis transverse to the longitudinal axis of the needle and defining a slot dimensioned for movement of the needle therethrough, the clip being rotatable from a first orientation to a second orientation to reposition the cavity relative to the longitudinal axis of the needle from a sliding orientation to a binding orientation... the clip including a first leg...the clip further including a second leg that extends from the plate and has a proximal part and a distal part, the distal part of the second leg including a bearing surface that engages the needle in both the first orientation and the second orientation of the clip...

Independent Claim 26 has been amended to recite, *inter-alia*, a safety needle shield comprising: a needle... a clip defining a first cavity...the clip being movable from a first orientation to a second orientation...the clip including a first leg that defines a second cavity dimensioned for movement of the needle therethrough, wherein the first leg has a distal part being configured to engage a medical device when the clip is in the first orientation, the clip further including a second leg having a bearing surface that engages the needle when the clip is in both the first orientation and the second orientation...

Independent Claim 27 has been amended to recite, *inter-alia*, a medical clip for use with a piercing member...the clip comprising: a first cavity dimensioned for movement of the piercing member... the clip being rotatable from a first orientation to a second orientation to reposition the first cavity relative to the longitudinal axis of the piercing member from a movable orientation to a binding orientation...a first leg...a second leg having a bearing surface configured to engage the piercing member in both the first orientation and the second orientation of the clip...

As shown in FIGS. 25 and 26, reproduced below, and as described in the specification, for example on page 19 lines, 23-33:

In the sliding orientation, bearing surface 642 engages the outer surface of needle cannula 22 to balance the convergent spring forces generated by legs 632, 640 and network 641. Correspondingly, legs 632, 640 are balanced about needle cannula 22 such that aperture 630 of aperture plate 660 is maintained in a sliding orientation. In the binding orientation, needle cannula 22 passes out of aperture 634 and bearing surface 642 facilitates inclination of clip 628. As legs 632, 640

convergent bias due to the resilience of spring elements 643 of network 641, bearing surface 642 engages needle cannula 22 causing clip 628 to rotate, relative to longitudinal axis x, aperture 630 into the binding orientation with needle cannula 22. Bearing surface 642 also engages needle cannula 22 in the binding orientation to prevent movement of needle cannula 22 in the proximal and distal directions.

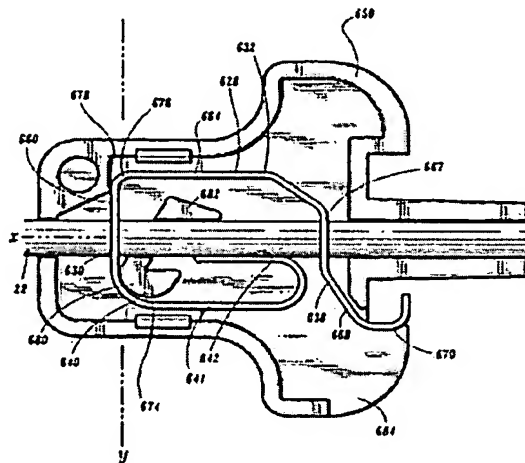


FIG. 25

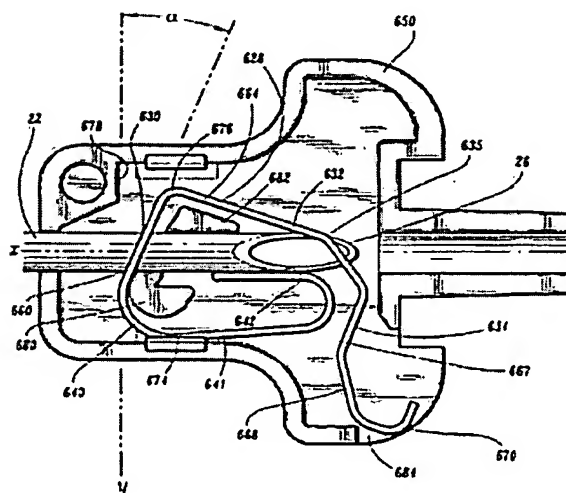
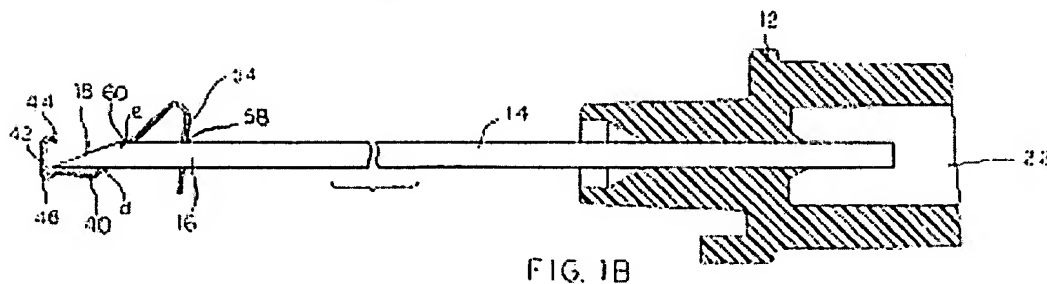
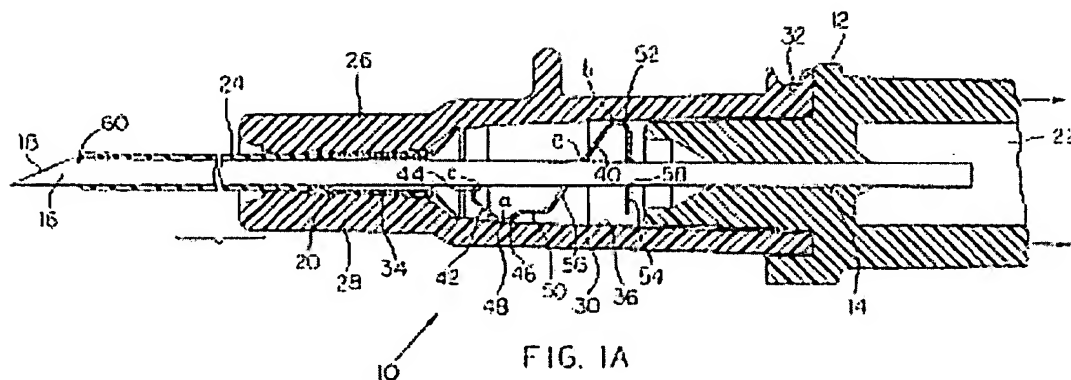


FIG. 26

In contrast, as illustrated in FIGS 1A and 1B, reproduced below, Woehr relates to a safety IV catheter including a needle hub 12 that includes an axial opening 14 which securely receives the proximal end of a needle 16 having a sharpened tip 18. (*See* col. 4, lines 14-18). As the needle 16 is withdrawn from the patient, a protective needle guard 40 located within hub chamber 36 automatically snaps into a retract position in which it blocks access to the distal needle tip 18. (*See* col. 4, lines 49-53). The needle guard 40 includes a resilient portion which comprises a distal arm 42 terminating at its upper end in a curved lip 44, and at its lower end in a pointed end 46, which is received with a mating groove 48 formed in the lower interior wall of catheter hub section 30. (*See* col. 4, lines 56-64). In the ready position of the catheter prior to needle withdrawal, the shaft of needle 16 engages the curved lip 44 of the spring clip needle guard 40, thereby to exert an essentially downward force on the resilient spring clip 40. That force causes the lower end 46 of the spring clip to seat securely in groove 48 at point a. That contact, in addition to the abutment of the upper end 52 of the spring clip with the upper interior wall at the catheter hub at point b, securely maintains the spring clip needle guard 40 in the ready position within the catheter hub. (*See* col. 5, lines 11-15).

As Woehr's needle 16 is retracted to the left, as viewed in FIG. 1A, to its fully retracted position shown in FIG. 1B, after catheter insertion into the patient's vein, the distal tip of the needle moves proximally past the curved lip 44 of the spring clip needle guard 40 at point c, at which time the downward force previously exerted by the needle shaft on the spring clip is released. As a result of the needle 16 moving proximally past point c, the retention force on spring clip needle guard 40 in the catheter hub is released causing the spring clip needle guard 40

to pivot or snap in a clockwise direction to the retracted position shown in FIG. 1B. (See col. 5, lines 27-32).



Accordingly, as recited in Claim 1, Woehr does not disclose, *inter alia*, a second leg having a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation. As recited in Claim 15, Woehr does not disclose, *inter alia*, a second leg that extends from the plate and has a proximal part and a distal part, the distal part of the second leg including a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation. Furthermore, as recited in Claim 20, Woehr does not disclose, *inter alia*, a second leg that extends from the plate and has a

proximal part and a distal part, the distal part of the second leg including a bearing surface that engages the needle in both the first orientation and the second orientation of the clip. As recited in Claim 26, Woehr does not disclose, *inter alia*, a second leg having a bearing surface that engages the needle when the clip is in both the first orientation and the second orientation. Further still, as recited in Claim 27, Woehr does not disclose, *inter alia*, a second leg having a bearing surface configured to engage the piercing member in both the first orientation and the second orientation of the clip.

In fact, Woehr's device teaches away from Applicant's claims as recited because Woehr's distal arm 42 necessarily completely disengages from the piercing member 16 in order to snap into the retracted position shown in FIG. 1B.

For at least these reasons, Applicants submit that independent Claims 1, 15, 20, 26 and 27 are patentable over Woehr and are in condition for allowance. Furthermore, since Claims 2-10, 12-14, 16-19, 21-22, 25, 28-29, 31 and 33 depend, either directly or indirectly from 1, 15, 20, 26 and 27, it is respectfully submitted that Claims 2-10, 12-14, 16-19, 21-22, 25, 28-29, 31 and 33 are at least patentable for the reasons that independent Claims 1, 15, 20, 26 and 27 are patentable. Accordingly, withdrawal of this rejection is respectfully requested.

Claim Rejections under 35 U.S.C § 103

In the Office Action, Claims 23 and 24 were rejected under 35 U.S.C. § 103(a), as being unpatentable over Woehr in view of U.S. Patent Application No. 2002/0193745 to Ferguson ("Ferguson"). Claims 23 and 24 each depend from Claim 1. Ferguson fails to cure the deficiencies of Woehr as discussed above with respect to Claims 1, 15, 20, 26, and 27. For at

least the reasons discussed above with respect to Claim 1, *inter-alia*, Applicants submit that Claims 23 and 24 are in condition for allowance. Thus, withdrawal of this rejection is respectfully requested.

In the Office Action, Claims 30, 34-36, and 38-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Woehr. Claims 30, 34-36 each depend from independent Claim 27 and Claims 38 and 39 depend from independent Claim 1. As such, for at least the reasons discussed above with respect to Claims 1 and 27, *inter-alia*, Claims 30, 34-36, and 38-39 are in condition for allowance.

In addition, independent Claim 40 has been amended to recite, *inter-alia*, a safety shield comprising: a piercing member...a clip defining a first cavity dimensioned for movement of the piercing member therethrough and being oriented in an axis transverse to the longitudinal axis of the piercing member, the clip being movable from a first orientation to a second orientation to reposition the first cavity from a movable orientation to a binding orientation...the clip including a first leg ... the clip further including a second leg having...a bearing surface that engages the piercing member in both the first orientation and the second orientation of the clip...

As discussed above with respect to independent Claims 1, 15, 20, 26 and 27, Woehr does not disclose, *inter alia*, a bearing surface that engages the piercing member in both the first orientation and the second orientation of the clip as recited in amended independent Claim 40. As such, for at least this reason, independent Claim 40 is in condition for allowance. Thus, withdrawal of this rejection is respectfully requested.

In the Office Action, Claims 32 and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Woehr in view of Ferguson. Claims 32 and 37 each depend from Claim 27.


As discussed above, Ferguson does not cure the deficiencies of Wochr with respect to Claim 27. As such, for at least the reasons discussed above with respect to Claim 27, Claims 32 and 37 are in condition for allowance. Thus, withdrawal of this rejection is respectfully requested.

In view of the foregoing, it is respectfully submitted that all of the claims pending in the application are in condition for allowance. With this in mind, reconsideration and allowance of this application is respectfully requested.

Applicants believe that all issues raised in the Detailed Action have been responded to fully. Should the Examiner believe that a telephone interview may facilitate resolution of any outstanding issues, the Examiner is respectfully requested to telephone Applicants' undersigned attorney at the number indicated below.

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,


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